aryl (C_{6-12}) and substituted aryl; M is hydrogen, sodium, potassium, ammonium, diethanolamine, cyclohexylamine, a naturally-occurring amino acid of MW less than 500 kD, lower alkyl (C_{1-6}), cycloalkyl, or aryl (C_{6-12}); and n is 0-5; or,

d) any combination thereof and,

a pharmaceutically acceptable carrier, diluent, or excipient.

REMARKS

I. Status of the claims and support for amendment

Claim 1 and 17 are amended.

Claims 1-18 are pending.

Support for the amendment of claim 1 is found in claims 5 and 18 as originally filed and at page 7, line 6-9 of the specification.

II. Response to the Examiner's Restriction

In the instant Office Action the Examiner has restricted the invention to four groups as follows:

Group I: Claims 1-4, 8, and 16.

Group II: Claims 5-7 and 9-15.

Group III: Claim 17.

Group IV: Claim 18.

For the reasons detailed below, Applicant believes that restriction of the claims in the instant application is improper. Evidence in support of Applicant's position is as follows.

A. In the Restriction Requirement, the Examiner quoting the MPEP stated that:

> [i]nventions are unrelated if it can be shown that they are not disclosed as capable of use together **and** they have different modes of operation, different functions, or different effects (MPEP §806.04, MPEP § 808.01).

(Page 3 of the instant Office Action, emphasis added). The Examiner then continued by alleging that "Group I has a different mode of operation than Group II." Applicant respectfully disagrees. Beyond mere assertion, Examiner has presented no data or reasoned argument to support the allegation that Group I and Group II claims have a "different mode of operation." Consequently,

Applicant asserts that Examiner has not established a that the claims of Group I and Group II have a "different mode of operation."

Furthermore, even if Examiner were able to substantiate this assertion, all of the criteria set forth by the standard (see above quote), which are required to show that the inventions are unrelated, have not been met. As set forth in the passage quoted above, in order to show that the inventions of Group I and II are unrelated the Examiner must establish both that the inventions operate by a different mode **and** that the inventions are "not disclosed as capable of use together." Applicant contends that the latter element cannot be established for Groups I and II. Group II claims depend from, and are a sub-set of the Group I claims. Therefore, by definition, they Group I claims must be capable of "use together" with Group II claims. Finally, Applicant asserts that the amendment of claim 1 which recites "or any combination thereof" effectively merges the Group I claims and the Group II into a single invention.

806.04!

B. As applied *mutatis matandis*, reasoning detailed in part "A.," above, also demonstrates that the claims of Group III and Group IV (*i.e.*, claims 17 and 18) are not patentably distinct from one another.

C. Applicant Asserts that the restriction of Groups III and IV from the Group I claims is improper for the following reasons. As cited by the Examiner:

> [t]he inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. (MPEP § 806.05(h)).

(*See*, page 4, first paragraph of the Office Action, emphasis added). Applicant contends that "as claimed" the process of the Group I and Group II claims can only be practiced using the compositions of the Group III and Group IV claims. Likewise, "as claimed," the compositions of the Group III and Group IV claims are specifically formulated for use in the methods of the Group I and Group II claims. Therefore Applicant believes that, within the scope of MPEP 806.05(h), restriction of the methods and composition claims is improper.

Furthermore, even if the restriction is deemed by Examiner to be proper within the purview of MPEP 806.05(h), Applicant contends that the restriction should not be maintained. MPEP § 803 recites, *inter alia*, that:

> [i]f the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions.

Applicant contends that examination of the Group I – Group IV claims in the instant application would not place a "serious burden" on the Examiner. The compounds claimed in the Group III and Group IV claims will be identified by any search required for the Group I and/or Group II claims. The Examiner has already indicated that the art related to the various inventions will be found within the same class (*i.e.*, Class 514 and subclasses 277, 564, 513, 438, 568). Thus, since the methods and the compounds will be identified by the same search there is no additional search burden and restriction is improper.

Furthermore, it is common practice in the Patent Office to examine "methods of treatment" claims and claims to "compositions/compound" used in those treatments in a single application, see for example U.S. Pat. No. 6,150,412 (which has claims to a method for treating Parkinson's disease and claims to compounds for use in that treatment), U.S. Pat. No. 6,150,380 (which claims (which has claims to a method for treating gastrointestinal disorders and claims to compounds for use in that treatment), U.S. Pat. No. 6,150,351 (which has claims to a method for treating diseases caused by *Helicobacter pylori* infection and claims to compounds for use in that treatment), and U.S. Pat. No. 6,146,653 (which has claims to a method for treating diabetes, in mammals, and claims to compositions for use in that treatment).

In view of the above remarks, Applicant respectfully requests that the restriction requirement be withdrawn. Nevertheless, in response to the restriction requirement which the Examiner imposed, Applicant elects, with traverse, to prosecute claims 1-4, 8, and 16, *i.e.*, the Group I claims.

III. Species Election

The Examiner has required that the Applicant must identify the species "consonant with the requirement set forth in 35 U.S.C. § 121 and list all claims readable thereon." Applicant responds as follows.

As the specie corresponding to the compound of Formula I, Applicant elects the sodium salt of phenylacetylglutamine (*i.e.*, in Formula I, R and R_1 are both hydrogen, R_2 is phenyl, M is sodium, and n is 0), which is read on by claims 1-8, 10-15, 17 and 18. As the specie corresponding to the compound of Formula III, Applicant elects the sodium salt of phenylacetylisoglutamine (*i.e.*, in Formula III, R and R_1 are both hydrogen, R_2 is phenyl, M is sodium, and n is 0), which is read on by claims 1-8, 17, and 18. Finally, as the specie corresponding to the compound of Formula IV, Applicant elects the sodium salt of phenylacetatic acid (*i.e.*, in Formula IV, R and R_1 are both hydrogen, R_2 is phenyl, M is sodium, and n is 0), which is read on by claims 1-12, 17 and 18.

IV. Conclusion

Applicant believes that all of the Examiner's requirements as set forth in the instant Office Action have been met. Applicant respectfully requests a favorable examination of all pending claims.

The Examiner is invited to contact the undersigned patent agent at (713) 787-1589 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,

Matthew Madsen

Matthew L. Madsen
Reg. No. 45,594
agent for Applicant

HOWREY SIMON ARNOLD & WHITE, LLP
750 Bering Drive
Houston, Texas 77057-2198
(713) 787-1400

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